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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,002

05/20/2005

Ugur Sahin

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MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER

REDDIG, PETER J

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

06/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,002

Applicant(s)

SAHIN ET AL.

Examiner

Peter J. Reddig

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99-104 and 107-115 is/are pending in the application.
- 4a) Of the above claim(s) 107-115 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 99-104 is/are rejected.
- 7) ☒ Claim(s) 103 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. The Amendment filed April 17, 2007 in response to the Office Action of October 17, 2006 is acknowledged and has been entered. Previously pending claims 105 and 106 have been cancelled, claims 99-104 have been amended. The examiner previously withdrew claims 107-115.

2. Claims 99-104 are currently being examined.

3. The following rejections are being maintained:

Priority

4. Receipt is acknowledged of the translation of the foreign priority documents papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

The disclosure of the prior-filed application, German Application No. 102 54 601.0, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for the claimed method of this application. The German Application No. 102 54 601.0 does not provide enabling support for diagnosing a cancer by detecting SEQ ID NO: 16 (claudin 18A2.1) because 102 54 601.0 only teaches detecting claudin 18A2.1 mRNA in tumors (see Example 4, p. 67-70, Table 3 and Fig. 5) and for the reasons set forth on pages 12-14 of the Office Action of October 17, 2006, the detection of mRNA does not predictably extrapolate to the detection of proteins. Additionally German Application No. 102 54 601.0 does not provide an adequate written description of diagnosing a cancer by detecting a portion of SEQ ID NO: 16, a portion of a polypeptide encoded by a nucleic acid of SEQ ID NO: 7, and a portion of a polypeptide encoded by a nucleic acid that hybridizes to a nucleic acid of SEQ ID NO: 7 for the reasons set forth on pages 22-25 of the Office Action of October 17, 2006 and below.

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Additionally, given that PCT/EP03/13091 was not published in English and thus does not meet the requirements of PCT article 11, the national stage entry of PCT/EP03/13091 does not have the effect of a national application for a patent regularly filed with the Office as of its international filing date under 35 U.S.C. 363. Thus, given that PCT/EP03/13091 does not provide enabling support for diagnosing a cancer disease by the detection of SEQ ID NO: 16 (see pages 16-21 of the Office Action of October 17, 2006 and below) nor an adequate written description of diagnosing a cancer by detecting a portion of SEQ ID NO: 16, a portion of a polypeptide encoded by a nucleic acid of SEQ ID NO: 7, and a portion of a polypeptide encoded by a nucleic acid that hybridizes to a nucleic acid of SEQ ID NO: 7 for the reasons set forth on pages 22-25 of the Office Action of October 17, 2006 and below, Examiner maintains the priority date of 5/20/2005 as previously set forth.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 99-104 remain rejected under 35 USC 112 as lacking enablement for the reasons previously set forth on pages 16-22 of Office Action of October 17, 2006.

Applicants argue that Examiner alleges that the instant application does not demonstrate activation of claudin-18A2 protein expression in any disease. Applicants argue that the data related to bronchial carcinoma was disclosed for the purpose providing an example and that, with respect to other cancer types disclosed in the present specification, protein expression data correlate with expression of mRNA. Applicants argue that, as such, the present application

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demonstrates that claudin-18A2 mRNA as well as claudin-18A2 protein is aberrantly activated in pancreas carcinomas, esophagus carcinomas and bronchial carcinomas as described in Table 3A and paragraph [0305] of the published specification. Applicants argue that for further clarification, the applicants have added the term "cancer" disease in claim 99. Applicants argue that specifying the disease to be diagnosed to specific cancer types would unduly limit the scope of the claims to the specific embodiments disclosed in the examples.

Applicant's arguments have been fully considered and have been found persuasive in part. While the specification is enabling for diagnosing stomach cancers and lung cancers by detecting the expression of Claudin-18A2 protein, the data presented in Table 3A and paragraph [0305] appear to measure Claudin-18A2 mRNA levels and for the reasons previously set forth on pages 16-22 of Office Action of October 17, 2006, mRNA expression does not predictably correlate with protein expression and thus does not provide enabling support for diagnosing any cancer by detecting Claudin-A2 protein, SEQ ID NO: 16. Thus, amending the claims to diagnosing a cancer disease does not overcome the rejection because the specification does not provide enabling support for the broad scope of the claims.

Applicant's arguments have not been found persuasive and the rejection is maintained.

6. Claims 99-104 remain rejected under 35 USC 112 as lacking an adequate written description for the reasons previously set forth on pages 22-25 of the Office Action of October 17, 2006.

Applicants argue that the Examiner alleges that the instant application concerns the detection of a portion of a claudin-18 protein or a polypeptide encoded by a portion of a claudin-18 nucleic acid, and therefore, it lacks an adequate written description. Applicants argue that to

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address the Examiner's concern, the Applicants have amended claims 99 and 100 to delete the term "portions thereof".

Applicant's arguments have been fully considered and have not been found persuasive because, although Applicants have deleted the term "or a portion thereof", given that the claims are still drawn to a polypeptide of SEQ ID NO: 16, a polypeptide encoded by a nucleic acid of SEQ ID NO: 7, and a polypeptide encoded by a nucleic acid that hybridizes to a nucleic acid of SEQ ID NO: 7, all which read on fragments of the claimed polypeptides, and thus diagnosing cancer based on those fragments, the rejection for lacking an adequate written description is maintained.

Applicant's arguments have not been found persuasive and the rejection is maintained.

New Claim Objection

7. Claim 103 is objected to because of the following informalities: There is a period after the word "a" before the end of the sentence. Appropriate correction is required.
8. All other objections and rejections recited in the Office Action of October 17, 2006 are withdrawn.
9. No claims allowed.
10. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application

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which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal form, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

11. The amendment to the claims necessitated the new objection. Thus, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

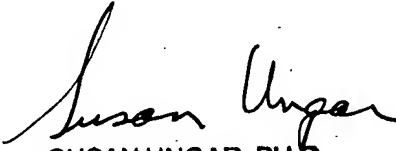
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on (571) 272-0890. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Peter J. Reddig, Ph.D.
Examiner
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SUSAN UNGAR, PH.D
PRIMARY EXAMINER

PJR